ANNEX 3

EXPERT PANEL ON PROCEDURES FOR THE EVALUATION OF THE HAZARDS OF HARMFUL SUBSTANCES CARRIED BY SHIPS

DRAFT REPORT OF THE MEETING

IMO Headquarters, London
23-25 August 1995

1 Introduction

1.1 The expert panel met at IMO Headquarters, London, from 23 to 25 August 1995. Dr. P. G. Wells chaired the panel; expert members of the panel are listed in annex 3-1.

1.2 The IMO Technical Secretary of GESAMP, Dr. M. Nauke, welcomed the panel members. He explained that this panel had been established on the recommendation of the Marine Environment Protection Committee (MEPC) of IMO for the following reasons:

.1 a review of the existing four pollution categories of noxious liquid substances in Annex II to the MARPOL 73/78 Convention is being carried out, together with the categorization guidelines which had been developed by IMO on the basis of the scientific hazard evaluation procedures established by GESAMP in 1972 for that specific purpose;

.2 the need to harmonize the IMO provisions for maritime transport of dangerous goods set out in the IMDG Code, with regulations developed within other fora for road and rail and inland water transportation. In this regard, support should be provided to the work of the UN Committee of Experts on the Transport of Dangerous Goods (ECOSOC) in establishing criteria for environmentally hazardous substances to be included in its Recommendations. This would be applicable for all transportation modes, taking into account the outcome of the OECD clearinghouse charged to harmonize the classification of environmentally hazardous substances. This OECD clearinghouse had agreed to adopt the classification criteria developed by the European Community and the Nordic countries as a starting point for the development of a common system concerning hazards to the aquatic environment; and

.3 comments made to MEPC by Greenpeace International that since the aquatic hazard evaluation carried out by GESAMP is based mainly on results of tests on aquatic acute toxicity, these do not provide a sound basis for determining potential hazards of substances discharged or spilled from ships into the marine environment and, in turn, the need for regulatory action.

1.3 MEPC had requested GESAMP to establish a joint IMO/GESAMP panel of experts to carry out a review of the hazard evaluation procedures. GESAMP at its twenty-fifth session (Rome, 24-28 April 1995) noted, however, that the Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships (EHS) was fulfilling its terms of reference in conducting the hazard evaluations, based on the intrinsic properties of chemicals. If a review of the terms of reference was to be requested, this would be a matter to be discussed solely within IMO.

1.4 Accordingly, IMO in establishing this panel called upon experts who were involved in IMO's regulatory work, expert members of the EHS Working Group, and experts from the European Chemical Industry Council (CEFIC) and Greenpeace International.

1.5 The agenda of the expert panel meeting is shown in annex 3-2. In a general discussion the chairman noted that the purpose of GESAMP's hazard evaluation was to provide suitable information for IMO to ensure that appropriate decisions are made regarding safe handling and transport of chemicals, and the discharge of of tank washings into the marine environment, and appropriate response to accidental spills. Thus the hazard profiles assist IMO in identifying pollution categories for noxious liquid substances carried in bulk, or to identify packaged goods as marine pollutants.. The current GESAMP hazard evaluation procedure was based on the intrinsic properties of the respective substances to identify a hazard but was **not** intended to represent risk, i.e., the procedure does not take into account the exposure conditions in the environment, and the probability of release of these substances into the environment.

1.6 The Secretary recalled that in the early 1970s IMO had requested GESAMP to prepare a hazard evaluation system concerning the potential effects of substances when released into the marine environment concerning:

- damage to living resources;
- hazards to human health;
- reduction of amenities; and
- interferences with other uses of the sea.

These potential effects reflected elements of the definition of "marine pollution" developed by GESAMP, as well as the definition of "harmful substance" contained in article 2(2) of MARPOL 73/78, meaning "any substance which, if introduced into the sea, is liable to create hazards to human health, to harm living resources and marine life, to damage amenities or to interfere with other legitimate uses of the sea, and includes any substance subject to control by the present Convention". The definition of marine pollution, implicitly reflected above, had been accepted in all international legal instruments on the protection of the marine environment, including UNCLOS 1982, since the 1970s.

2 Hazard to aquatic organisms

2.1 Acute aquatic toxicity

2.1.1 In evaluating hazards to marine life GESAMP has used acute aquatic toxicity data, expressed whenever possible as median lethal concentrations (48 to 96hr LC_{50}/EC_{50}) for marine fish and crustacean species. The need for caution had been expressed by GESAMP for the use of such data for predicting environmental risks to marine life. GESAMP had considered the use of acute toxicity test data as the most practical solution in order to rank the hazards posed to living resources, but was well aware that for some persistent and bioaccumulative substances, adverse effects may manifest themselves after short or prolonged exposures to much lower concentrations than those that are acutely lethal, and that these may in the end be more important in their effect on the marine ecosystem.

2.1.2 The expert from Greenpeace International noted that in his view behavioural, narcotic and chemoreceptive capabilities were often demonstrated at concentrations considerably lower than at 96hr LC_{50}. He further noted that acute lethal toxicity data on their own were of limited usefulness for addressing the potential long-term effects of chemicals on the marine ecosystem. Other panel members fully supported this view, recognizing the difficulties in using aquatic toxicity data for the purpose of predicting long term marine environmental risks without consideration of other data reflecting potential long-term effects.

2.1.3 The panel recommended that acute toxicity data from a minimum of three different species of different trophic levels, namely a fish, a crustacean and micro-algae, should be used. The panel also emphasized that other stages in the life cycle of organisms can be more sensitive than those that are usually the subject of routine or regulatory acute toxicity testing. It noted that early life stages were often included

in the acute toxicity test in any case. GESAMP should continue to take into account the lowest toxicity thresholds available from fish, crustacea and algal tests. The panel noted that GESAMP had always preferred that marine species be used in acute aquatic toxicity testing of chemicals submitted for evaluation; however it had emphasized that it was most important that the data were generated from tests carried out on the basis of internationally agreed guidelines.

2.1.4 The panel recommended that tests should be conducted according to internationally accepted guidelines and be performed to good laboratory practice (GLP). It was felt to be important to request that all test results be provided together with their confidence limits and other appropriate statistics. Estimates based on QSAR calculations should be clearly identified as such. The panel also emphasized that LC_{50} values should be based on measured concentrations and that the methodologies used should be described.

2.2 Chronic toxicity effects

2.2.1 The expert from Greenpeace International reiterated his view that the standard tests accepted by GESAMP for the purpose of MARPOL 73/78 do not provide information necessary to assess long-term effects on species' composition, on populations and the health of ecosystems. There are a number of biological test procedures that could be applied to provide the necessary information.

2.2.2 Whilst the panel fully recognized the validity of Greenpeace's comments in relation to the ultimate risks of introducing a hazardous or dangerous chemical into the marine environment, it was also recognized that there were practical constraints in recommending such evaluation for all substances carried by ships. However, there were substances for which long-term toxicity data were available. GESAMP should use results of chronic tests to complement standard information in cases where there was suspicion of particular potential adverse effects that were not expressed by results of acute toxicity tests.

2.2.3 The panel recommended that substances for which there were reasons to suspect that they might pose particularly adverse effects to the marine environment, but there was no definitive scientific evidence, should be regarded as candidates for review. Data on potential long-term effects or chronic toxicity should be requested for detailed evaluation.

2.3 Indirect lethal effects

The panel noted that a number of solid cargoes have been assessed which, if spilled in substantial quantities, blanket the seafloor rendering it unsuitable for benthic life, and that such an indication had been reflected in the hazard profile. The panel could not find any reason to discontinue such a practice. The panel asked the EHS Working Group to consider the possibility of recording potential indirect lethal effects caused by physical properties of solid substances and by physical properties of liquid substances (e.g., persistent non-toxic floaters) together in one column of the hazard profile.

2.4 Biodegradability

2.4.1 The panel confirmed that in hazard assessments of substances discharged into the marine environment the main question besides that concerning toxic properties, was whether the substance is likely to persist in the marine environment. Persistence is generally defined in terms of ability to resist biodegradation. The panel noted that even the release of small quantities of highly persistent but less toxic substances could still present harm to the marine environment, particularly if it had bioaccumulative properties; this might result in long-term damage. Persistence was considered within the EC scheme to be a key adverse property. The Greenpeace expert noted that degradation products would have to be included in the hazard evaluation process, using as an example hexachlorobenzene which biodegrades through the complete series of chlorinated benzenes.

2.4.2 The Panel was informed that the European Union scheme classifies any substance that is not biodegradable (either not readily biodegradable as defined in one of several standard tests, or not degraded >70% in real water, i.e., sea water (closed bottle test)) and with acute LC_{50} <100 mg/l as "harmful to aquatic organisms". Specific measures are also requested for identification, evaluation and risk assessment of "persistent organic pollutants (POPs)" in UNEP's Global Plan of Action for the prevention of marine pollution from land-based activities (Washington DC, 23 October to 3 November 1995).

2.4.3 Dr. Hanstveit informed the panel of the role of biodegradability testing and evaluation of respective results within other international regulatory bodies, e.g., the European Union, the Oslo and Paris Commissions, the latter body applying results of biodegradability testing in the classification of chemicals discharged from offshore installations at sea. "Ready Biodegradability" of substances introduced into the environment, including marine compartments, is used worldwide and tests to measure these properties are available, originally for freshwater, but since the early 1980s these have been adapted for use involving marine environments. Ready biodegradability implies a complete degradation of an organic chemical to natural inorganic components and biomass without formation of persistent and toxic metabolites. The OECD biodegradability testing methods are classified in three groups, i.e., ready biodegradability tests (OECD 301A-F), inherent biodegradability tests (OECD 302A-C), and simulation tests (OECD 303A). The OECD Ready Biodegradability Tests of the "301 series" are applicable to freshwater systems for a wide range of chemicals. Biodegradation is measured as the difference in oxygen consumption (301C, D, F), DOC removal (301A, E) or carbon dioxide evolution (301B) between vessels containing a known amount of test substance and controls. Seawater versions of DOC die-away and closed bottle methods (301D, E) have been ring-tested and guidelines for the marine version (the OECD 306 series) were published in the early 1990s. These use nutrient-enriched, natural coastal seawater. Comparability studies have shown that readily biodegradable chemicals identified in freshwater tests have also been identified as biodegradable in the marine environment. However, the conditions in the marine environment may be quite different from those found in freshwater. The main difference is the oligotrophic conditions in seawater characterized by relatively low concentrations of organic substances and chemical/biomass ratios. Although the biodegradation rate may be found to be lower in seawater than in freshwater, seawater is considered to have a high capacity for biodegradation of chemicals. This is an additional argument for the use of the ready biodegradability criterion for the marine environment.

2.4.4 Measurements of "inherent biodegradability" are carried out with other test methods listed in the OECD 302 test series, using pre-adapted sewage sludges and bacterial inocula. The panel noted that this was not appropriate for use in assessing the hazards of substances discharged from ships into the marine environment. Research has also demonstrated that the biodegradability of inherently biodegradable substances in the marine environment cannot be reliably predicted by current laboratory testing methods.

2.4.5 With regard to "abiotic degradability", it was understood that this was related to hydrolytic, photochemical and other physical processes in the marine environment, and therefore was relevant for carrying out risk assessments, rather than from hazard assessments in the context of MARPOL 73/78.

2.4.6 The panel recommended that the addition of a simple Yes/No "ready biodegradability" rating would be a very useful addition to the current hazard profiles; this would, however, not include measurements of "inherent biodegradability" (see paragraph 2.4.4 above). The inclusion of biodegradability ratings would facilitate the harmonization between IMO regulations concerning maritime transportation of dangerous packaged goods with provisions adopted by other organizations for different transportation modes.

2.5 Bioaccumulation, including biomagnification, bioconcentration and biotransformation

2.5.1 The panel recalled that GESAMP uses three hazard ratings for bioaccumulation in its column A:

+ = Bioaccumulated to significant extent and known to produce a hazard to aquatic life or human health

Z = Bioaccumulated with attendant risk to aquatic organisms or human health, however with short retention of the order of one week or less; and

O = No evidence to support one of the above ratings.

2.5.2 In adopting these ratings GESAMP had originally emphasized that accumulation was not necessarily harmful and in some cases with naturally occurring substances may even be beneficial, and that the hazard evaluation procedure should recognize such harmless accumulation. It had also been felt that at that time the hazard evaluation procedure should distinguish between those substances that have a long residence time in the animal and are harmful, and those that are harmful but have a shorter residence time in the animal. In recent years more attention has been directed to situations where substances may be altered in the environment, and as a consequence become more readily bioaccumulated and harmful. Some compounds are degraded or metabolized fairly readily but yield products that are either equally or more harmful (e.g. some PAHs).

2.5.3 The panel advised that the bioaccumulation potential of organic chemicals should be assessed in using both log Pow data and measured bioconcentration factors (BCF). Any harm that could be identified due to bioaccumulation processes would be expressed through other ratings, e.g., on toxicity to marine life and potential effects on human health. In a study, one of the panel experts comparing measured and calculated log Pow and bioconcentration data for 75 organic chemicals, demonstrated that a simple numerical rating system could be used for a future column A (Bioaccumulation) column:

- log Pow calculated >5, together with BCF, calculated as being above 10000 would result in a bioaccumulation rating of "5";

- log Pow calculated 4-5, together with BCF (calculated) 1000 - 10000 would be rated "4";

- log Pow calculated 3-4, together with BCF (calculated) 100-1000 would be rated "3";

- log Pow calculated 2-3, together with BCF (calculated) 10-100 would be rated "2"; and

- log Pow calculated <2, together with BCF (calculated) 0-10 would be rated "1".

2.5.4 The panel noted that this system, as far as the 75 organic chemicals used in the study were concerned, was in good agreement with measured log Pow values and measured BCF data available through open literature, indicating that more than 100-fold bioaccumulation could be expressed through its log of the octanol:water partition coefficient (log Pow) exceeding the value of 3. This had already been expressed by GESAMP in Reports and Studies No.35 when establishing a criterion for Z ratings. Likewise, in the European classification system, substances with a log Pow ≥ 3 and a measured BCF >10 are regulated.

2.5.5 Several members of the panel suggested that the outcome of further scientific studies on effects linked with log Pow and BCF should be awaited before setting up a numerical rating system with defined thresholds.

2.5.6 Other members of the panel expressed the view that for the hazard evaluation of a substance that is bioaccumulated, its aquatic toxicity as well as other factors, e.g., hazard to human health, should continue to be taken into account.

3 Hazards to human health

3.1 Acute toxicity (peroral, cutaneous, inhalation)

3.1.1 The degree of hazard posed to human life through ingestion of contaminated water has long been assessed through the use of oral LD_{50} data, taking into account that such data were generally available. Where dilution is a factor, oral toxicity may not be a relevant consideration. The panel noted that the EHS Working Group at its thirtieth session had considered the possibility of including cutaneous and inhalation routes since these are equally and, in some instances, more important routes of exposure. It was therefore proposed that the "Hazard to human health" column (C) should have three sub-headings to compare the oral (peroral),cutaneous (percutaneous) and inhalation routes and that these be expressed as numerical ratings from 0 to 4 based on LD_{50} or LC_{50} ratings.. The highest value would form the basis for overall rating.

3.1.2 The panel generally agreed that such information would allow the user of the hazard profiles to compare absolute and relative hazards by the three exposure routes and between different materials. However, several members felt that a single rating representing the most appropriate exposure route was more appropriate and practical.

3.2 Irritancy and sensitization

3.2.1 The EHS Working Group at its thirtieth session had suggested that the immediate hazards of skin and eye irritation and corrosion be included separately from other (long-term) health effects in hazard profile column D. In this column skin and eye irritation and corrosion should be separately expressed on a numerical scale. The panel also drew attention to the fact that certain delayed or cumulative effects can develop subsequent to a single exposure or repeated exposures to certain substances. In this connection the remarks column should continue to be used to draw attention to materials which could produce cumulative, delayed or other specific long-term adverse effects. The remarks column should also draw attention to significant noxious or physical effects. A rating system could be included as a third sub-heading in column D.

3.2.2 The panel agreed that the abbreviated legend to the hazard profiles (Rep.Stud.No.35, annex 5) needs to be clarified and updated in order to more precisely describe the human health hazards that have been identified by GESAMP and used in establishing the hazard profile. This should include a list, with definitions, of specific adverse health effects that are considered. Consistency in terminology was essential.

3.3 Human health hazards in relation to pollution incidents as a result of marine transport

The panel considered it important that potential pollution situations be identified where edible material could become contaminated with toxic materials or metabolites that could lead to human health problems. Those substances known or suspected to cause long-term or cumulative adverse health effects were regarded as being of particular concern. A combination of bioaccumulation, persistence, and known human adverse health effects were considered as criteria for inclusion in this category. The means by which such materials are identified in the hazard profile needs careful consideration.

3.4 Protocols for mammalian toxicology and related studies

Information used for the evaluation of human health effects comes from a variety of sources, including laboratory studies. Since such studies are costly, have been conducted in a variety of laboratories, and many precede GLP regulations, they require detailed interpretation. Particular attention should be paid to the study objectives and design (including monitoring), methodology employed, details of recording

results, statistical analysis, and interpretation of results. Only scientifically acceptable studies will be used to determine potential human health hazards for the purposes of assignment of a hazard profile.

4 Other effects and interferences

4.1 Tainting

4.1.1 The panel noted that in previous GESAMP evaluation procedures the identification of substances liable to taint living resources when discharged or spilled at sea had been given high priority. This was based on the assumption that, in the case of spillages at sea of tainting substances, fishing areas and coastal aquaculture were affected and would have to be closed for a certain period of time even in those cases where incidents were relatively short-lived. A chemical does not have to bioaccumulate to induce taint to living marine organisms. Fish can be tainted rapidly, often within a few hours after a spill occurs. In cases where the chemicals partition into lipids of the organisms, the taint can be retained for a long time, even when the organisms are no longer exposed to the chemical.

4.1.2 The panel recommended that the tainting rating "T" should be maintained, and that this be included in a column under the heading "Other uses of the sea". The panel noted that there was very little data available on tainting. Data on odour detection thresholds of chemicals in aqueous solution can be used to predict the potential for tainting and such data have been used by the EHS Working Group for allocating "T" ratings to substances carried by ships. The chemical industry had been informed through EHS meeting reports on tainting test procedures and studies on odour detection thresholds. Draft guidelines for odour detection threshold have been issued in EHS reports. Industry was invited to comment on the proposed test guidelines . Measurements of odour detection thresholds would reduce the more sophisticated and more expensive tainting tests with fish. The industry representatives stated that additional testing for tainting of substances that have already been categorized under MARPOL 73/78 would inflict high costs without leading to further safety requirements for handling and transport of those substances.

4.1.3 The panel expressed the view that the capacity of a substance to taint fish and to influence the smell and taste of water when spilled on land or into aquatic environments should merit consideration by bodies responsible for the classification of environmentally hazardous substances involved in land-based transportation modes. CEFIC pointed out that the relevant IMO bodies considered the exclusion of the criterion "liable to taint seafood" for future classification of packaged dangerous goods. In this context the industry experts provided information on minimum requirements for United Nations testing and categorization of packaging and provisions for land transport of packaged goods. As a result of these requirements and related provisions, large and unrecoverable accidental spillages due to transportation were very rare, certainly in Europe.

4.2 Reduction of amenities

4.2.1 The panel confirmed that the current evaluation procedure for the rating of impacts on coastal amenities, derived from a wide range of considerations, including physiochemical properties (e.g., to cover explosive, flammable, oxidizing substances, etc.) of substances that might be washed ashore, as well as their long-term health effects, was well established. However, the various criteria would need to be defined and described in a much more precise way than previously. The panel agreed that the current process under column E was appropriate.

4.2.2 Besides the impact of substances washed up on beaches, a column "Reduction of amenities" may be used to record impact on marine life caused by other physical properties of the substances concerned, e.g., harmful effects on birds and marine mammals as well as effects caused by bulk solids or viscous and cohesive substances on coral reefs or mangroves.

5 Provision of data and information

The panel briefly reviewed the form distributed to industry to supply relevant information and data needed by GESAMP to evaluate the hazards of chemicals proposed for transport at sea. The panel agreed that the current form should be revised as soon as possible and distributed through the official channels. There were only a few additional items of information and data that would be necessary for use in a revised evaluation procedure. However, more attention should be given in a revised form to sources of information and data that are being submitted by industry, e.g., whether data had been derived from measurements of or tests carried out with particular products, determined in analogy with similar products, or taken from literature. The necessity to identify data sources should be emphasized at the top of the revised questionnaire.

6 Mixtures

6.1 The panel considered problems encountered by the EHS Working Group in relation to the carriage of mixtures under trade or generic names, which require a hazard profile before they can be assigned a pollution category.

6.2 It was noted that hazard evaluations have been carried out for mixtures transported under trade or trivial names. In such cases relevant data have been obtained from tests with the mixtures as carried at sea. The panel very strongly emphasized that in these cases a description of the composition of the mixtures should be requested, together with assurance that the composition of the mixture would be within stated limits. In other cases where mixtures were of clearly defined components that had been evaluated separately, the hazard profile of the mixture is based on its most hazardous components.

6.3 It was emphasized that hazard profiles assigned to trade-named mixtures should not be used for substances carried under similar trade-names, unless information had been provided by the manufacturers that the composition was within the stated limits as mentioned above.

6.4 Concern was expressed by the expert from Greenpeace International that the hazards of mixtures were in general underrated due to potential synergistic effects of the various components, noting that it was the position of several national scientific institutions that there was currently no way of reliably assessing the toxicity of mixtures of chemicals, whether the effects were antagonistic, synergistic or additive.. Other experts noted that there were very few identified examples of synergistic effects in spite of considerable research efforts, especially on organics.

6.5 The expert from Greenpeace International further pointed out that surfactants, emulsifiers and impurities might increase the toxicity of some chemicals. The panel noted that this matter was currently being researched.

7 Closure of the meeting

Members of the panel expressed their appreciation for having been given the opportunity to exchange valuable information during the meeting, resulting in fruitful discussion. The chairman thanked all members for their co-operation, suggesting that this expert meeting should be considered as a starting point for future workshops involving experts from non-governmental and governmental institutions.

ANNEX 3-1

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ANNEX 3-2

AGENDA FOR THE EXPERT PANEL

1 Introduction

2 Hazards to aquatic organisms

- 2.1 acute aquatic toxicity
- 2.2 chronic toxicity effects
- 2.3 indirect lethal effects (physical impacts)
- 2.4 degradability, including biotic, abiotic)
- 2.5 bioaccumulation, including biomagnification, bioconcentration and biomodification

3 Hazards to human health

- 3.1 acute toxicity (peroral, cutaneous, inhalation)
- 3.2 Irritancy and sensitization
- 3.3 human health hazards in relation to pollution incidents at sea
- 3.4 Protocols for mammalian toxicology and related studies

4 Other effects and interferences

- 4.1 tainting of seafood
- 4.2 reduction of amenities (e.g. beaches, mangroves, coral reefs)

5 Provision of data and information

6 Mixtures

7 Closure of the meeting

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